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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/799,534 | 03/12/2004 | Long Sheng Yu | 76982-Z/JPW/JSW | 7819 |

23432 7590 10/04/2010
COOPER & DUNHAM, LLP
30 Rockefeller Plaza
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NEW YORK, NY 10112

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| EXAMINER |
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ALTER, ALYSSA MARGO

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| ART UNIT | PAPER NUMBER |
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3762

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10/04/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/799,534 | YU ET AL. | |
| | Examiner | Art Unit | |
| | Alyssa M. Alter | 3762 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 April 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 and 12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 26, 2010 has been entered.

Response to Arguments

Applicant's arguments filed June 19, 2008 have been fully considered but they are not persuasive.

The Applicant argues that the grafting tube is not “an adjustable attachment member that extends or retracts from an end of the inflow tube” since it is constructed from non-collapsing material. While the Applicant is correct in reciting that Kahn et al. discloses the grafting tube is made of non-collapsible material, this does not preclude the tube from compressing or extending in the longitudinal plane, i.e. to extend or retract the tube. Kahn et al. states that the tube is non-collapsible in the horizontal plane, i.e. to ensure the tube does not collapse and halt blood flow. The compression or extension of the tube, which comprises a spring, is therefore inherent.

Additionally, the Applicant argues that the inflow tube does not have a rotatable end. However, the connection would necessarily be rotatable since the connectors can be rotated to facilitate engagement.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1. Claims 1-3 and 7-10 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Kahn et al. (US 3,766,567).

Kahn et al. discloses an artificial heart assembly that is connected to the ventricular apex of the heart, as seen in figure 8. The infow adapter 88 is the “inflow tube”, and the arterial grafting tubing 87 and tubular extension 86 are considered to be the “adapter sleeve”, with the arterial graph tubing functioning as the “adjustable attachment member for attaching the adapter sleeve to the inflow tube” of the “adapter sleeve”. Since the “arterial graft tubings 87 and 92 are made of flexible, non- collapsing materials, for

example, spirally wound metal wire covered with silicone” (col. 6, lines 37-39) they are necessarily flexible and compressible. Therefore, silicone coated member would necessarily be able to extended or retracted to a certain degree.

In the alternative, Kahn et al. discloses the device substantially as claimed by is silent as to the ability of the tubing’s capability to “extend or retract”. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the tubing material to permit extension or retraction in order to provide the predictable results of modifying the tubing to be capably of insertion into a child or adult without adversely affecting the structural integrity of the tubing.

As to claims 2-3 and 7, also seen in figure 8 is the sewing flange 76. Furthermore, the examiner considers the sewing ring to function as a gripping member to attach the inflow tube to the ventricular apex.

As to claim 8, as seen in figure 8, since the inlet and outlet of the inflow tube are at different angles, there is necessarily a bend in the tube.

As to claims 9-10, “built into the assist adapters 88 and 89 are connectors 90 and 91 like the connector 22 of FIGS. 6 and 7 for easy attachment to the connectors 23 and 27 on the ventricle 11”(col. 6, lines 31-33). Thus the end of inflow tube 88 that connects to connector 90 is extendable, as seen in figures 6 and 7. Furthermore the examiner considers the connection to be rotatable since the connectors can be rotated to facilitate engagement.

As to claim 11, the examiner considers the valve 21 (fig. 6) to be an inner sleeve.

2. Claims 4, 6 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable

over Kahn et al. (US 3,766,567) or the modified Kahn et al. as applied to claims 1-3 and 7-10 above. Kahn et al. discloses the claimed invention but does not disclose expressly the titanium or ceramic material. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the adapter sleeve as taught by Kahn et al., with a titanium or ceramic adapter sleeve, because Applicant has not disclosed the titanium or ceramic material provides an advantage, is used for a particular purpose, or solve a stated problem. One of ordinary skill in the art, furthermore, would have expected the Applicant's invention to perform equally well with the adapter sleeve as taught by Kahn et al., because both materials are biocompatibility and frequently incorporated in implantable devices.

Therefore, it would have been an obvious matter of design choice to modify the material for titanium to ceramic to obtain the invention as specified in the claim(s).

Furthermore, Kahn et al., discloses the claimed invention except for the titanium or ceramic material. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the material to ceramic material, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice.

In re Leshin, 125 USPQ 416 (See MPEP 2144.07)

3. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kahn et al. (US 3,766,567) or the modified Kahn et al. as applied to claims 1-3 and 7-10 above. Kahn et al. discloses the claimed invention except perforations on the adapter sleeve. It would have been obvious to one having ordinary skill in the art at the time the invention

was made to modify the device of Kahn et al. with grooves forming perforations in order to provide the predictable results of customizing the size of the adapter sleeve in order to modify the device to meet specific patient needs. For example, a child may need an adapter that differs in size than an adult.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alyssa M. Alter whose telephone number is (571)272-4939. The examiner can normally be reached on M-F 8am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Niketa Patel can be reached on (571) 272-4156. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Niketa I. Patel/
Supervisory Patent Examiner, Art Unit 3762

/Alyssa M Alter/
Examiner
Art Unit 3762